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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,837	07/23/2001	Klaas Poelstra	P 280101	6405

22242 7590 07/24/2003

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CHICAGO, IL 60603-3406

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,837

Applicant(s)

POELSTRA ET AL.

Examiner

Janet L. Andres

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV and species election of liver fibrosis in Paper No. 14 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search all species. This is not found persuasive because the species are not linked by cause, tissue of origin, or method of treatment. Thus they are independent inventions lacking a linking special technical feature and as such require different searches. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of Group IV has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL. Claims 1-26 are pending in this application. Claims 1-7, 14, and 16-26 are under examination as they pertain to the elected sequence of SEQ ID NO: 3 and the elected species of liver fibrosis.

Information Disclosure Statement

The information disclosure statement filed 12 May 2003 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. The abstract has been considered.

Specification

The disclosure is objected to because of the following informalities: There are sequences on pp. 4, 5, and 9 that lack sequence identifiers. The sequence rules require that all unbranched amino acid sequences of four or more specifically defined amino acids be referred to by the identification number of an entered sequence wherever they appear. See MPEP§ 2421.02

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Appropriate correction is required.

The brief description of the drawings is objected to because it does not describe figures 1-4 and because it should precede the detailed description of the invention. In addition, the “description of the drawings” on p. 10 is incomplete. See MPEP §608.01(a) for the requirements for the arrangement of the application.

Claim Objections

Claims 1-7 are objected to because of the following informalities: They are in improper form. The correct terminology for a Markush group is “selected from the group consisting of”. Appropriate correction is required.

Claims 4-7, 14, and 16-26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from another multiple dependent claim. See MPEP § 608.01(n).

Claims 1-7 and 16-26 are objected to as encompassing non-elected subject matter. Claims 16-26 are also objected to as depending from non-elected claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25 and 26 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter. A “use” is not a proper process claim under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 14, and 16-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of targeting albumin to hepatic cells using the peptide of SEQ ID NO: 3, does not reasonably provide enablement for methods and compounds targeting other tissues, for the treatment of disease not involving the liver, for any diagnostic purpose, or for other conjugates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Applicant has shown that albumin modified by the cyclic peptide of SEQ ID NO: 3 can be used to target the liver. However, the claims encompass all cells involved in "sclerotic or fibrotic disease". No examples have been presented to show that any other tissue could be targeted, and no other guidance is provided that would render such targeting predictable. Applicant has shown only that the modified albumin targets the liver; there is no objective evidence to indicate that this targeting is dependent on fibrosis; the binding is the same in controls as in fibrosis. Thus there is no indication that the peptide could be used diagnostically;

the binding does not change with disease. There is no evidence to indicate that other tissues, when damaged, would be targeted by the peptide. The mere statement that PDGF receptors are upregulated in other diseases is not sufficient to allow the skilled artisan to predictably use the peptide to target other tissues. Since there appears to be no difference between normal and fibrotic liver, PDGF receptor levels are not predictive of binding. Further, example 4 indicates that the cyclic peptide by itself does not bind to PDGF receptors; only the complex with albumin does. Thus, one of skill in the art would not be able to determine what is responsible for targeting to the liver, and would predictably be able to use the peptide of SEQ ID NO: 3 complexed with anything else, since it appears that albumin is as necessary for binding as the peptide. Thus, without further guidance to indicate that the peptide complexed to other agents would bind, without further guidance to indicate that other tissue types could be targeted, and without further guidance as to how binding could be used diagnostically, it would require undue experimentation for one of skill in the art to use the invention as claimed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

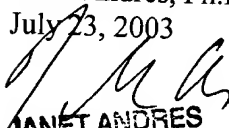
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
July 23, 2003


JANET ANDRES
PATENT EXAMINER